

WLO 30 87

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
25 July 2002 (25.07.2002)

PCT

(10) International Publication Number
WO 02/058307 A2

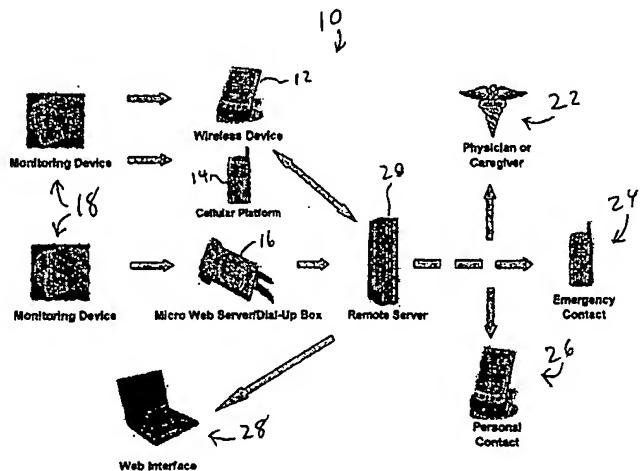
- (51) International Patent Classification⁷: **H04L** CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.
- (21) International Application Number: **PCT/US02/01941**
- (22) International Filing Date: 22 January 2002 (22.01.2002)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
60/263,345 22 January 2001 (22.01.2001) US
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- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: ELECTRONIC HEALTH/DATA MANAGEMENT SYSTEM WITH ACTIVE USER PARTICIPATION



WO 02/058307 A2

(57) Abstract: A system combines electronic monitoring devices, data accumulation and the Internet to provide the tools necessary for active participation and proactive treatment in health management. Consumers are continuously connected to a caregiver, with ability to transmit real-time vital signs for interactive review. Through the use of a live connection, an electronic monitoring device transmits readings, via an Internet platform, to a monitoring location where the data values are measured against predetermined thresholds. If the readings are outside acceptable ranges, a physician or caregiver as well as a personal contact is notified by any communication medium, and instructions are issued. Any communications link may be used between the monitoring device and a database storage server. The electronic device may communicate with the transmission portal, enhancing accessibility, mobility and functionality, for transmission of real-time data from any electronic device.

**ELECTRONIC HEALTH/DATA MANAGEMENT SYSTEM
WITH ACTIVE USER PARTICIPATION**

FIELD OF THE INVENTION

5 The present invention relates to computer and network-based systems for managing health care, and in particular to an electronic system and method for enhanced management of health care and health-related data with active user participation.

BACKGROUND OF THE INVENTION

10 It is a common observation that there is something amiss in America's healthcare delivery system today. If that observation were reduced to a word it would be dissatisfaction. The cause of the discontent depends on whose vantage point the healthcare delivery system is viewed from. For physicians it is the overarching pains caused by managed care and government regulation. For the managed care plans it is the 15 constant struggle not to manage care but to manage costs. For the patient it has been a never-ending cycle of understanding complex HMO rules and plan books and a de-personalization in the historic relationship between a patient and their doctor. For the employer, there is the recognition that healthcare costs are rising, and that they are now facing double-digit premium increases that implode on the bottom line. In addition, for 20 over 43 million Americans, there is the fact that they simply have no medical coverage at all and are perhaps one illness away from medical insolvency.

 The first step toward the alleviation of healthcare dissatisfaction is not found within the medical profession, within managed care companies or from the passage of

more legislation. Rather, the next step to be taken in healthcare needs to come from consumers themselves.

The only way America's healthcare system will ever be suitable is for the consumer to become a participant rather than a spectator.

5 The incipient focus of change must come from those consumers who have or will be facing a chronic disease condition for which active management is a prerequisite to the state of their physical, mental and perhaps even spiritual health. By the year 2010 it is estimated that 120 million Americans, about 40% of the total population, will be living with a chronic disease. With forecasted patient expenditures of \$600 billion for the year
10 2010, a 16% increase from the present, this market is poised to obtain the benefits of electronic efficiencies. Internet (Net)-capable devices are an answer to the exorbitant increase in medical costs. For example, cost-effective, virtual office exams will ease the burden on caregivers, while also improving the quality of care. The key to extended health is early intervention and this is only possible through connectivity, mobility and
15 reliability.

However, heretofore, Net-capable devices have not provided sufficient connectivity, versatility, or ease-of-use for facilitating health-data management to provide active user/patient/consumer participation.

Today, the treatment of chronic diseases accounts for 79% of healthcare
20 expenditures. To the disconnected consumer, this treatment often amounts to visiting a health provider for episodic acute incidents only after their condition has gotten beyond self-management. The problem with this approach is self evident: chronic conditions, by their very nature, are ongoing, daily and persistent ailments which must be dealt with in

much the same manner as we regulate our time of eating, going to work or watching television. Today's approach of a chronic patient visiting the doctor every 3 months for a check up belies the fact that for the other 89 days internal, external and environmental factors are impacting their illness in a manner that may not automatically comply with the 5 visit schedule. Yet the consumer as a spectator dutifully follows orders and simply relies on the hope that their condition will remain static during the interim between visits. Too often that is not the case, resulting in rushed trips to the emergency room or panicked calls to a caregiver in the middle of the night.

To become a participant in one's own care, a consumer needs the appropriate 10 tools. Some argue that the consumer will not reach for those tools until the cost of care is visited upon them by increased deductibles or denial of payments or the bankruptcy of their managed care plan. On the contrary, a participatory consumer is a cost effective consumer. Further, today's spectator consumer wants to become a participant consumer but the tools just don't exist.

15 A need exists for such consumer-based tools to permit a consumer/user/patient to be an active participant in the acquisition, monitoring, and updating of health-related data reflecting his/her condition.

SUMMARY OF THE INVENTION

20 An electronic health/data management system and method are disclosed which combine electronic monitoring devices, data accumulation and the Internet to provide the tools necessary for active participation and proactive treatment in health management. Consumers are continuously connected to a caregiver, with ability to transmit real-time

vital signs for interactive review. Through the use of a live connection, an electronic monitoring device transmits readings, via an Internet platform, to a monitoring location where the data values are measured against predetermined thresholds. If the readings are outside acceptable ranges, a physician or caregiver as well as a personal contact is 5 notified by any communication medium, and instructions are issued.

Any communications link, such as hard-wired and/or wireless channels, may be used between the monitoring device and a database storage server. The electronic device may communicate with the transmission portal, enhancing accessibility, mobility and functionality, for transmission of real-time data from any electronic device.

10

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 illustrates the components of the disclosed health/data management system.

FIG. 2 illustrates a block diagram of the components of an electronic health 15 device used in the system of FIG. 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

As shown in FIG. 1, the disclosed health/data management system 10 is shown, referred to herein as "the Diadem system" or "Diadem", developed by Next Generation 20 Health Networks, which includes a plurality of electronic devices for transmitting health-related data associated with a consumer/user/patient (hereafter "consumer") to a remote device, such that the health-related data may be processed, analyzed, and otherwise used

to allow health-care providers to monitor the consumer's health and/or to give medical instructions.

Each consumer has or otherwise accesses an electronic health device to transmit health-related data associated with the consumer. The electronic health device may be a 5 personal digital assistant (PDA) or other wireless computing devices 12, may be a cellular platform 14 associate with a cellular telephone, and/or may be any known data communications interface device 16, such as a micro-web server/dial-up box. Each electronic health device is connected and/or connectable to known data input devices including monitoring devices 18, such as pulse monitors, glucose level detectors for 10 diabetics, and even electronic weight scales.

In an alternative embodiment, the data input device may be a personal computer or other data acquisition devices which may store health-related data from other sources, such as a personal or family-based database of health data such as pulse counts, glucose counts, daily weight measurements, etc.

15

COMPONENTS OF THE DIADEM SYSTEM

Each electronic health device 12-16 is capable of connecting to a remote device, such as a remote server 20, to transmit the health-related data to the remote device. The remote server 20 is accessible by physicians 22 and/or other care givers such as hospitals, 20 as well as emergency contacts 24 and personal contacts 26. Such contacts 24-26 may include individuals such as personal doctors and/or relatives or friends who may act if the health-related data reflects an emergency or other dangerous health conditions, such as

excessively high glucose levels for diabetics. Such contacts 24-26 may then act to contact the consumer and/or appropriate medical personnel.

The remote server 20 may accessible via any known device available to the physician/caregiver 22, emergency contact 24, and personal contact 26, such as through 5 PDAs, cellular phones, or other communications and/or computing devices, including Internet-based devices.

In addition, the health-related data captured and stored by the remote server 20 may be accessible through the Internet using a World Wide Web (WWW or Web) interface 28. The consumer may view his/her own health-related data which, over a span 10 of time of monitoring, may show important patterns in the health of the consumer. In other embodiments, the health-related data may be accessed by health maintenance organizations (HMOs) or other concerned entities. In another embodiment, the consumers may be military personnel in the field, including at sea, in the air, or in space, whose health-related data may be acquired by wireless monitoring devices in the field, 15 compiled and stored in a remote server 20, and accessed via the web interface 28 by military superiors or medical staff in bases far distances from the individual military personnel being monitored.

COMPONENTS AND OPERATION OF THE ELECTRONIC HEALTH DEVICES

20 Referring to FIG. 2, each electronic health device 12-16 may include the components shown in the unit 30, including an input interface 32, a memory 34, a microcontroller 36, and a connection interface 38. The input interface 32 may be any known data port and/or circuitry, such as a Universal Serial Bus (USB)-compatible

interface, connected to the data input device 18 such as the monitoring devices described herein, for receiving the health-related data.

The memory 34 may be random access memory (RAM) and/or other known storage devices, such as floppy disks, for storing the health-related data. The memory 34 5 may also include the read only memory (ROM) of the microcontroller 36 and/or any memory or storage devices used for the interfaces 32, 36, which may include interface connection cards.

The microcontroller 36 may be a microprocessor for executing software implementing the Diadem system 10 in a manner described herein to establish the data 10 connections to receive the health-related data from the input devices 18 and to transmit the health-related data, in an appropriate data transfer format or protocol, to the remote server 20. For example, the microcontroller 36 may be an "INTEL PENTIUM"-based microprocessor running the "MICROSOFT WINDOWS CE" operating system to implement the Transmission Control Protocol/Internet protocol (TCP/IP) for 15 communications over the Internet to the remote server 20 and/or to the data input/monitoring devices 18.

In one embodiment, the microcontroller 36 periodically polls the data input device 18 to receive current and/or stored health-related data. For example, the microcontroller 36 may poll the device daily at a preset time, such as at 3 A.M. The operations of the 20 unit 30 and the Diadem system 10 may be automatic, so such polling may be performed at the preset time when the consumer is not or would not be testing.

In another embodiment, the microcontroller 36 polls the data input device 18 at regular intervals, such as every second, to provide real-time and/or substantially real-time

monitoring of the consumer, as well as real-time and/or substantially real-time reporting of such acquired health-related data to the remote server 20.

In a further embodiment, the data input device 18 may notify the microcontroller 36 when new health-related data is available, and then the unit 30 establishes a 5 communications connection to the data input device 18 to access the most current health-related data.

The microcontroller 36 accesses the health-related data in the memory 34, and also modifies, translates, and/or formats the health-related data for transmission to the remote server 20. For example, the monitoring device, as the data input device 18, may 10 generate individual glucose level values, and the monitoring device and/or the unit 30 may timestamp each value and store the values and associated timestamps in a "MICROSOFT ACCESS" database. The microcontroller 36 then formats the database of values and timestamps in a known manner for transmission using, for example, the TCP/IP format for data transmission to the remote server 20.

15 The microcontroller 36 modifies the health-related data using predetermined translation and formatting software to format the health-related data to comply with a transmission protocol used by the connection interface 38 and/or the modem 40.

The connection interface 38 may include, incorporate, or be connected to a 20 modem 40, connected to the remote server 20, for transmitting the modified health-related data for transmission to the remote server 20.

In one embodiment, the unit 30 is configured for mobile use, with the modem 40 being external to the unit 30 and/or to the microcontroller 36. The microcontroller 36 connects to the modem 40 using a wireless data transmission connection for transmission

of the modified health-related data from the modem 40 through the Internet to the remote device.

In an alterative embodiment, the unit 30 is configured to be positioned in a home and/or other fixed locations such as an office where the consumer works, a gym or 5 restaurant, or other types of buildings having wired and/or wireless telephone communications in a fixed location.. Alternatively, the unit 30 may be in a fixed location in a vehicle having independent communications facilities, such as a ship or airplane with wired and/or wireless telephone transmission, with the wired connections when the ship or airplane are stationary.

10 In the alternative embodiment with the unit 30 in a fixed location, the modem 40 is disposed internal to the unit 30, and the connection interface 38, including the modem 40, is connected through a plain old telephone system (POTS) line connection for transmission of the modified health-related data through the Internet to the remote server 20.

15 In another alternative embodiment, the connection interface 38 may include and/or be integrated with the input interface 32, for example, using common communications protocols and ports of the unit 30, and/or using the modem 40 to connect to the data input devices 18 as well as the remote 20, as appropriate, under the control of the microcontroller 36. For example, in this alternative embodiment, the microcontroller 20 36 performs a first procedure to access and retrieve the health-related data using the communications interface 38, and switches to perform a second procedure to transmit such health-related data, with appropriate translation and formatting, to the remote server through the communications interface 38.

The remote server 20 may be connected to the unit 30 through the modem 40 using an Internet Service Provider (ISP) and/or any other connections, entities, or communications channels to and/or through the Internet, such wired, wireless, and/or satellite communications. Alternatively, the remote server 20 may itself be a Web server 5 of the Diadem system 10 and/or a hospital of the physical/caregiver 22 which is a member of the Diadem system 10.

ADVANTAGES AND USES

The Diadem system is the first healthcare system designed to involve the 10 consumer while recognizing the chronic disease process as an event that must be monitored and managed daily. Diadem combines affordable physiologic monitoring devices, data accumulation and the Internet to provide the tools necessary for active participation and proactive treatment.

For the first time, patients are continuously connected to a caregiver 22, with 15 ability to transmit real-time vital signs for interactive review. Through the use of a broadband or dial-up connection, a medical device transmits readings, via an Internet platform, to a monitoring location where the data values are measured against predetermined thresholds. If the readings are outside acceptable ranges, a physician 22 or caregiver as well as an emergency contact 24 or a personal contact 26 may be notified by 20 telephone, E-mail, cell phone, or personal digital assistant (PDA), and health-care instructions are issued. A personal computer or vital signs monitor is not required, but may be used to enable the delivery of additional informational content, health planning services, as well as a higher level of condition participation.

No longer is a patient tethered by his or her condition. The Diadem system 10 fits easily into everyday life, as the consumer no longer needs to sacrifice connectivity for mobility. The system 10 may function anywhere a phone or broadband port is present. Be it on a plane or a ship, in a restaurant or on the subway, the consumer is able to record meaningful data to effectively manage and mitigate occurrences.

With the consumer as a participant, the future of healthcare is much more promising. The Diadem system 10 may be extended to encompass all aspects of remote and connected care. Diadem 10 provides solutions to numerous healthcare delivery deficiencies in areas such as:

10 1. Home Health

In the prior art, one can surf the Web while cooking or shop by television set, but tools did not exist to electronically "medify" the home. However, using the Diadem system 10, a house may provide connected care specific to the habits of an individual. Through the use of biosensors, wireless applications and proprietary medical devices, the Diadem system 10 provides the platform to a totally connected, non-intrusive health system. In some embodiments, driven by a robust voice recognition system, artificial intelligence and the Internet, Diadem 10 is able to provide a medically wired house suited to the daily routine of an individual. A consumer may take a pulse oximetry reading using a data input device/monitoring device 18 while brushing his/her teeth, record a blood pressure scan while sitting in front of the television or monitor glucose levels while working on the computer, etc. In addition, the consumer can receive and transmit information by way of a screen built into the bathroom mirror or on a tablet PC

in the kitchen using, for example, the Web interface 28. Diadem 10 provides the tools necessary for interactive, meaningful in-house health management.

2. Cellular/Wireless Care

Cellular and wireless providers are proceeding with an increasing 5 emphasis on unit functionality. The Internet, news clips as well as two-way messaging are only a few examples of programs available from such devices which may be used as the units 30 embodied as or incorporated in any type of electronic health devices 12-16. The Diadem system 10 presents the opportunity to provide meaningful health management tools over a cellular or wireless platform as well as receive and transmit 10 real-time data and/or near real-time. The Diadem system 10 may use known hardware, including off-the-shelf and/or proprietary hardware, to enable the interaction between a cell phone and medical monitoring devices. The Diadem application may be, for example, written in Java2ME for increased functionality, and may reside on the cellular or wireless platform to enable constant interaction with care.

15 3. Electronic First Aid

The Diadem system 10 enables the first Internet driven first aid kit. Through connectivity and interactivity, the electronic kit provides meaningful information to a caregiver and facilitate a higher level of care while recording a history record of incidences. Data may be transmitted over any telephonic port (phone line, cell 20 phone, PDA, satellite phone) and is therefore transplantable into most any location or situation.

4. -- Travel Care

Diadem 10 provides a consumer with the ability to travel anywhere without having to forego connectivity and continuity of care. The same tools that are available at home will be made available for travel purposes as well. No longer will a consumer need to travel in fear of an episodic incident due to a disconnection of care.

5. Ease of Use

Diadem 10 provides a solution that easily fits into everyday life and incorporates meaningful information to better manage health and increase quality of life. This approach provides the bridge from spectator to participant in a meaningful way most likely to achieve the goal of creating tomorrow's health consumer.

CLAIMS

WHAT IS CLAIMED IS:

1. An electronic health device capable of connecting to a remote device to transmit health-related data to the remote device, the electronic-health data device comprising:
 - an input interface connected to a data input device for receiving the health-related data;
 - a memory for storing the health-related data;
 - a microcontroller for accessing the health-related data in the memory, andfor modifying the health-related data for transmission to the remote device; and
 - a connection interface, including a modem, connected to the remote device, for transmitting the modified health-related data for transmission to the remote device.
- 15 2. The electronic health device of claim 1, wherein the electronic health device is configured for mobile use;
 - wherein the modem is external to the microcontroller; and
 - wherein the microcontroller connects to the modem using a wireless data transmission connection for transmission of the modified health-related data from the modem through the Internet to the remote device.

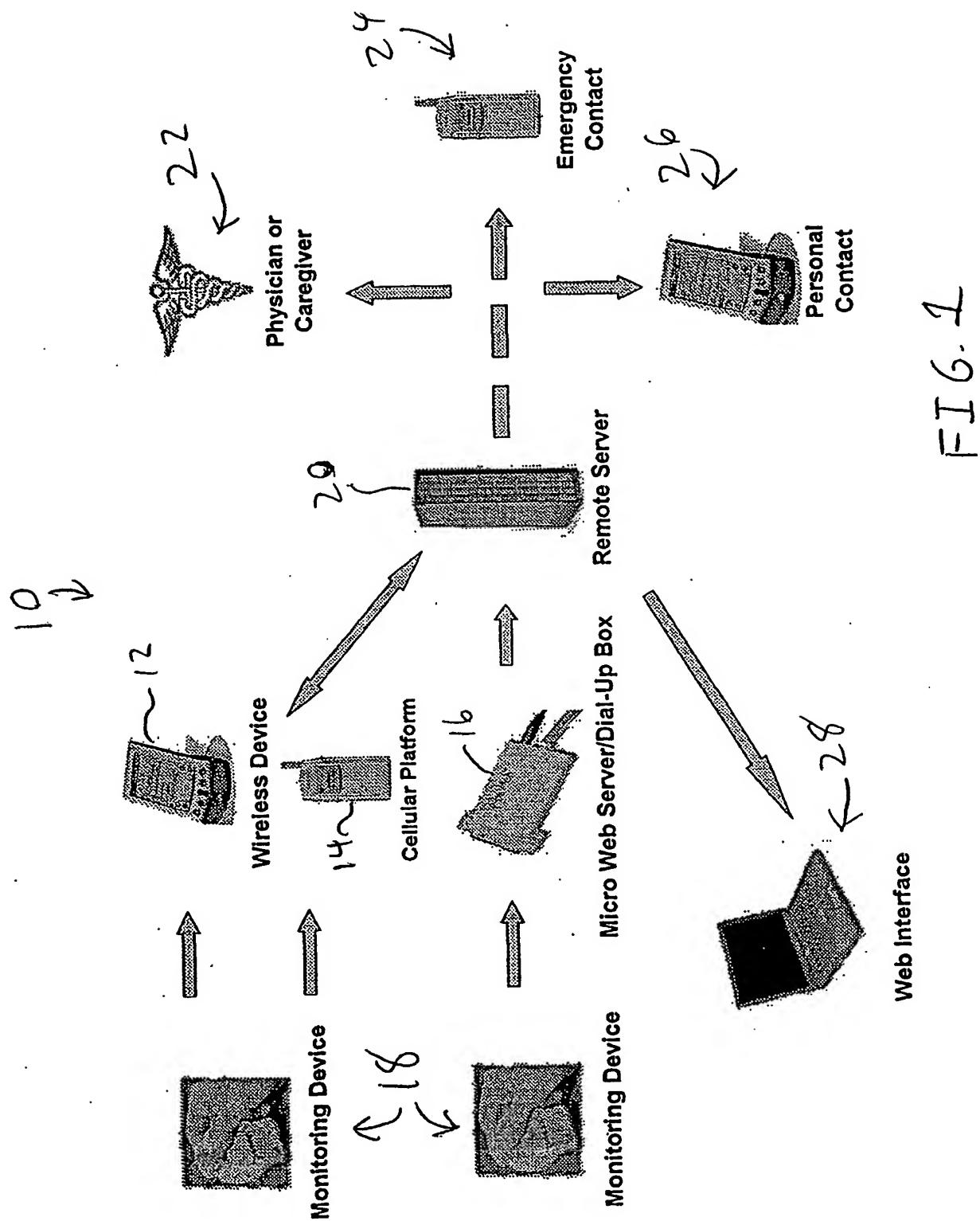


FIG. 1

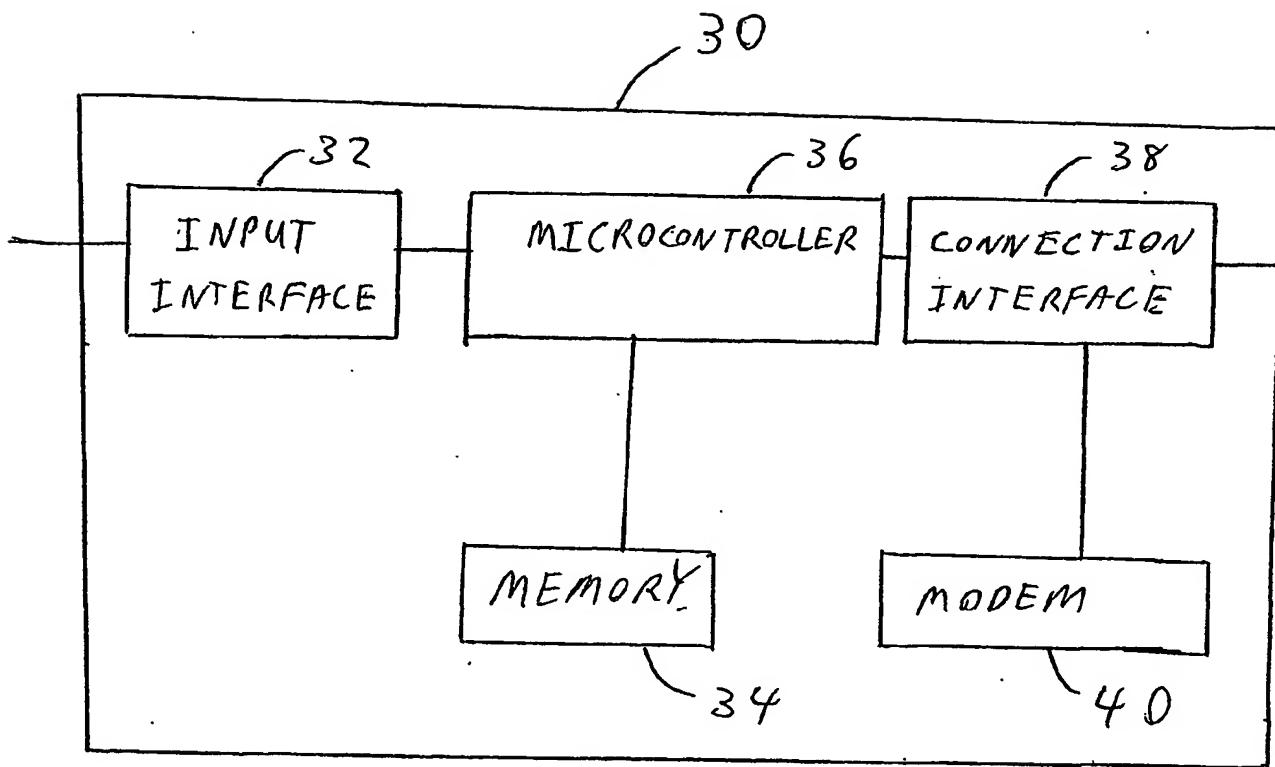


FIG. 2